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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,197	03/27/2001	Satomi Nishikawa	P278064	3685

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EXAMINER

LOEB, BRONWEN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,197

Applicant(s)

NISHIKAWA ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 9. 6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

This action is in response to the communication filed 13 September 2002.

Claims 1-12 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 and 3-10 as read on SEQ ID No. 1 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that there is not an undue burden to search all the inventions and that they are all novel and nonobvious. This is not found persuasive because the instant case is a national stage application under 35 USC §371 and therefore, the restriction is based on lack of unity in accordance with the Patent Cooperation Treaty. Lack of unity does not consider undue burden therefore this is not a persuasive grounds to rebut the restriction. Furthermore, rejoinder practice is relevant only to restriction practice in applications filed under 35 USC §111 and is thus not applicable to the pending application.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

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and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no computer readable format (CRF) was filed, no paper sequence was filed and no attorney statement was filed. These sequences include **p. 28, oligonucleotides A-D; p. 29, oligonucleotides E and F; pp. 30, 31, 32, 54 and 55, oligonucleotides G and H; pp. 33 and 39, oligonucleotides I-L; p. 43, oligonucleotides P and Q; p. 44, oligonucleotides R and S; p. 45, oligonucleotides S-U; pp. 49 and 56, oligonucleotides M and K; pp. 50 and 57, oligonucleotides U and K; p. 51, oligonucleotides M and G; p. 52, oligonucleotides M and N; and p. 53, oligonucleotides M and O.** If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Any reply to a notice to comply with the sequence rules comprising a computer readable format should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office because mail sent to this zip code is destined for irradiation. Computer readable formats, such as disks and CD's, are destroyed as a result of the irradiation process. The following information is also provided on the website.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebc/efs/downloads/documents.htm>
>, EFS Submission User Manual - ePAVE)

2. Mailed to:
**U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202**

3. Mailed by Federal Express, United Parcel Service or other delivery service to:

**U. S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Box Sequence
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202**

4. Hand Carried directly to the Customer Window at:

**2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,
Arlington, Virginia 22202**

Specification

4. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

Drawings

5. Applicant's attention is drawn to the Draftsperson's Patent Drawings Review, Form 948, attached to this action.

Claim Objections

6. Claims 1, 3, 4, 7, 9 and 10 are objected to because of the following informalities: Claims 1, 4 and 7 each recite non-elected subject matter. Claim 1 recites SEQ ID No.
7. Claims 4 and 7 refer to claim 2. Claims 3, 4, 9 and 10 would be improved by amending them as follows:

- replacing the phrase “characterized in that it comprises” with the word “comprising” (claims 3 and 4);
- inserting the word “operatively” before the word “linked” (claims 3 and 4);
- deleting the phrase “in the form capable of functioning” (claims 3 and 4);
- replacing the phrase “characterized in that it carries” with the word “comprising” (claim 9);
- deleting the word “characterized” (claim 10); and
- replace the word “that” with “which”.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 9 is rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter.

Claim 9 recites “a transformant”. The specification teaches that animal cells may be used in such a transformant. Humans are animals; this claim therefore reads on a human transformant. Claims reading on human beings are non-statutory subject matter.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1 and 3-10 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. §112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written

Description" Requirement published in the Federal Register (Volume 66, Number 4, Pages 1099-1111).

Claim 1 is drawn to a promoter comprising DNA (b), which is a DNA that comprises a nucleotide sequence in which one or more bases are deleted, substituted, or added in the nucleotide sequence shown in SEQ ID No. 1 and which has more than 90% identity to the nucleotide sequence of any region consisting of 250 bp or more within the nucleotide sequence of SEQ ID No. 1. This is a genus claim in terms of any fragment which has more than 90% identical to any region of at least 250 bp of SEQ ID No. 1. The specification mentions SEQ ID No. 1. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all promoters comprising DNA (b) based on the teachings in the specification. The specification does not teach *any* 250 bp fragment of SEQ ID No. 1 which functions as a promoter. There is no correlation between sequence (structure) and the promoter function provided at all to indicate which 250 bp fragments would have promoter activity. There is no correlation to indicate in any 250 bp fragment, which 10% of positions could be altered and yet maintain promoter function. Therefore, the specification does not describe the claimed promoters comprising DNA (b) in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these promoters at the time of filing the present application. Thus, the written description requirement has not been satisfied.

11. Claims 3, 4 and 6-10 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. §112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 66, Number 4, Pages 1099-1111).

Claims 3 and 4 are drawn to a chimeric gene comprising a desired gene. Claims 6 and 7 are drawn to a vector comprising a desired gene. These are genus claims in terms of any gene. "Gene" refers to an entire genomic structure encompassing all the regulatory regions (5' untranslated and 3' untranslated regions) as well as exons and

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introns. A representative number of eukaryotic genes is not known. Thus, the written description requirement has not been satisfied with respect to the word "gene".

This rejection would be overcome by amending the claims to recite "coding region".

12. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 8 and 9 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague and indefinite as it is drawn to a method but lacks any active method steps. Amending the claim to recite: "A method of producing a transformant comprising introducing into a host cell any one of a promoter of claim 1, a chimeric gene of claim 3 or 4 and a vector of claims 5, 6 or 7" would overcome this rejection.

Claim 9 recites the limitation "the host cell" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1 and 3-10 are rejected under 35 U.S.C. §102(e) as being anticipated by Torikai et al (USP 5,959,176).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. §102(e). This rejection under 35 U.S.C. §102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Torikai et al teach a plant promoter sequence (nucleotides 1792 to 2038 of SEQ ID No. 2) which has more than 90% identity to a region consisting of at least 250 bp of SEQ ID No. 1. See also the alignment shown for Accession No. AR076817 (Database GenEMBL. Accession no. AR076817. Sequence 2 from USP 5,959,176 to Torikai et al, published 09-1999. Accessed 23 September 2002). Nucleotides 1798-2048 of SEQ ID NO. 1 in the instant invention is a fragment of 251 basepairs. Within this 251 basepairs there are 25 differences from nucleotides 1792 to 2038 of SEQ ID No. 2 of Torikai et al. This difference results in greater than 90% identity between the two sequences

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(226/251=0.90039). Torikai et al teach chimeric coding sequence comprising the promoter and a terminator, a plasmid comprising the promoter and the chimeric coding sequence, a microorganism or plant cell comprising the promoter or chimeric coding sequence or plasmid, and a method of producing a transformant comprising the promoter, the chimeric coding sequence or the plasmid. See entire document, including the claims and col. 3, line 1- col. 4, line 64.

Conclusion

Claims 1 and 3-10 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Customer service for Tech Center 1600 may be reached at (703) 308-0198.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

December 1, 2002

Donald D. Hepp
PATENT EXAMINER
Art Unit 1636